

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION**

UNITED STATES OF AMERICA ET AL.
ex rel. RAYBURN ALEX THOMPSON,

Plaintiffs

v.

APOLLO PATH, LLC D/B/A APOLLO
LABORATORIES; APOLLO
LABORATORIES SERVICES, LLC; ARBOR
DIAGNOSTICS, INC.; KORENVAES
MANAGEMENT, LLC; DAVID KEY;
BRIAN OLIVER; and MAX KORENVAES

Defendants.

Civil Action No. 3:20-cv-2917-D

**DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF
THEIR MOTION TO DISMISS AMENDED COMPLAINT**

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Relator's First Amended Complaint ("FAC") asserts that four distinct entities—Apollo Path, LLC D/B/A Apollo Laboratories ("Apollo Labs"); Apollo Laboratories Services, LLC ("ALS"); Arbor Diagnostics, Inc. ("Arbor"); and Korenvaes Management, LLC—and three individuals—David Key; Brian Oliver; and Max Korenvaes (collectively "Defendants")—each, separately, violated the False Claims Act ("FCA"), 31 U.S.C. §§ 3729–3733.¹ Relator asserts that Defendants knowingly presented false claims because they violated the Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b(b), and the Eliminating Kickbacks in Recovery Act of 2018 ("EKRA"), 18 U.S.C. § 220.

Relator's theory and causes of action are inconsistent with the AKS's and EKRA's plain language, have been rejected by courts, and are directly contrary to circuit precedent. As a result, Relator does not plausibly plead a cause of action under Federal Rule of Civil Procedure 12(b)(6). Additionally, Relator does not connect the multiple Defendants to actions that purportedly violate the AKS, EKRA, and/or the FCA, and, hence, his FCA claims should be dismissed under Federal Rule of Civil Procedure 9(b).

I. BACKGROUND

A. FAC's Allegations and Procedural Background

Relator filed his lawsuit more than four years ago, on September 22, 2020, on behalf of the federal government and four States: Texas, Oklahoma, Tennessee, and Massachusetts. *See* ECF 2. Relator alleges that Defendants violated the FCA because they had a policy of hiring independent contractor sales representatives who interacted with physicians, medical practices,

¹ The FAC also names Double Helix Management, LLC, as a Defendant. We understand that entity has not been served and, hence, it is not addressed as part of this motion.

and facilities that referred blood and toxicology specimens for testing to Apollo Labs or Arbor and paid those sales representatives based upon the profitability of the referrals Apollo Labs or Arbor received from those physicians, medical practices, and facilities. *See* FAC ¶¶ 2, 21 (ECF 52). Relator does not contend that these sales representatives paid kickbacks to the physicians, medical practices, or facilities to refer specimens to Defendants or that the sales representatives paid kickbacks directly to patients to have their specimens sent to Defendants. Instead, Relator believes that both EKRA and the AKS prohibit laboratories from hiring independent contractor sales representatives and paying them commissions based on their sales. *Id.* ¶¶ 2, 4.²

Relator asserts that the alleged “wrongdoing” occurred from at least 2015 and persisted at least until December 2019, when Relator left his employment. *Id.* ¶ 5. Relator contends that Defendants violated the AKS throughout this relevant time period and that they breached EKRA starting after October 24, 2018, when EKRA was enacted. *Id.* ¶ 250. As to EKRA, Relator claims relief under the FCA for claims “covered by Government Healthcare Programs.” *Id.* DOJ investigated Relator’s allegations and, on May 20, 2024, notified the Court that it was refusing to intervene in Relator’s lawsuit. *See* ECF 32. Each of the four States has similarly refused to participate in Relator’s lawsuit. *Id.*

After service of Relator’s initial Complaint, Defendants immediately moved to dismiss, pointing out that Relator’s contentions are contrary to Federal Rules of Civil Procedure 9(b) and

² If this case is litigated beyond the pleading stage, Defendants will demonstrate that Relator’s contentions are wrong, and that the sales representatives were, in fact, employees. For purposes of this memorandum, however, Defendants assume Relator’s factual allegations are correct to demonstrate that even if deemed true (which they are not), Relator’s allegations should be dismissed under Federal Rule of Civil Procedure 12(b)(6).

12(b)(6) and are clearly prohibited under circuit court authority, such as, Relator’s assertion that he possessed a private cause of action under the AKS. *See* ECF 50 at 20–21. While it appears that Relator has dropped this claim, his remaining claims are just as invalid and should be dismissed as well.

B. Legal Background

According to Relator, Defendants violated the FCA because they purportedly “falsely” certified compliance with the AKS and EKRA when, according to Relator, they knew that they were out of compliance with those statutes. *See* ECF 52 ¶ 4.

1. The AKS

The AKS prohibits a person from “*knowingly and willfully*” paying “*remuneration*” to “*induce*” the “*refer[ral] of an individual*” for which payment is made under a Federal health care program. Specifically, the AKS provides:

(2) Whoever **knowingly and willfully** offers or pays any **remuneration** (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person **to induce** such person—

(A) **to refer an individual** to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, ...

shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$100,000 or imprisoned for not more than 10 years, or both.

42 U.S.C. § 1320a-7b(b) (emphasis added).³ In 2010, Congress amended the AKS to clarify that a violation of the AKS can only result in an FCA violation if the alleged unlawful remuneration

³ *See also United States v. St. Junius*, 739 F.3d 193, 210 n.18 (5th Cir. 2013) (“To sustain a conviction under the Anti-Kickback Statute, the Government must prove the following elements beyond a reasonable doubt: (1) the defendant solicited or received any **remuneration**, including any kickback or bribe, directly or indirectly, overtly or covertly, in cash or in kind, to any person; (2) that the remuneration was solicited or received **to induce** such person **to refer an individual**”)

caused the referral of an item or service that is presented on a federal healthcare claim. *Id.* § 1320a-7b(g) (“[A] claim that includes items or services *resulting from* a violation [of the AKS] constitutes a *false or fraudulent claim* for purposes of the [FCA].” (emphasis added)).

First, to establish that defendants *knowingly and willfully* paid *remuneration* to induce referrals, the government must establish, at a minimum, that defendants knew that their conduct was wrongful and acted with a “bad purpose.” *See United States v. Shah*, 95 F.4th 328, 350 (5th Cir. 2024) (finding that to “prove a violation of the AKS, the Government must prove that the defendant acted willfully, that is, with the specific intent to do something the law forbids or with bad purpose either to disobey or disregard the law” (internal quotations, citations and footnotes omitted)); *see also United States v. Nora*, 988 F.3d 823, 830-31 (5th Cir. 2021) (same and reversing AKS conviction because no proof of willfulness when evidence did not show that employee understood the company’s “various practices and schemes to be fraudulent or unlawful, and thus there was insufficient evidence to conclude that [he] acted with ‘bad purpose’ in carrying out his responsibilities”); *United States v. Ricard*, 922 F.3d 639, 648 (5th Cir. 2019) (“Willfulness in the Medicare kickback statute means that the act was committed voluntarily and purposely with the specific intent to do something the law forbids; that is to say, with bad purpose either to disobey or disregard the law.” (internal quotation marks and citation omitted)); *cf. St. Junius*, 739 F.3d at 210 (noting that the “Government must prove that the defendant willfully committed an act that violated the [AKS]”).

to a person for furnishing or arranging of an item or service; (3) that the item or service was one for which payment may be made in whole or in part under a federal healthcare program; and (4) that the defendant acted **knowingly and willfully.**” (emphasis added) (citation omitted)).

Second, to establish that a claim for payment “includes items or services *resulting from*” an AKS violation for purposes of bringing an FCA action, a plaintiff must prove, as two appellate courts have pointed out, that “the harm would not have occurred in the absence of—that is, but for—the defendant’s conduct.” *U.S. ex rel. Cairns v. D.S. Med. LLC*, 42 F.4th 828, 834–35 (8th Cir. 2022) (quoting *Burrage v. United States*, 571 U.S. 204, 211 (2014)) (internal quotation marks omitted); *U.S. ex rel. Martin v. Hathaway*, 63 F.4th 1043, 1052 (6th Cir. 2023) (finding that “[w]hen it comes to violations of the [AKS], only submitted claims ‘resulting from’ the violation are covered by the [FCA]” and the “ordinary meaning of ‘resulting from’ is but-for causation”). As applied to the AKS and FCA, a plaintiff must therefore “prove . . . that the defendants would not have included particular ‘items or services’ absent the illegal kickbacks.” *Cairns*, 42 F.4th at 835 (citations omitted).

Appellate courts have observed that Congress erected the high “knowing and willful” intent and required “but-for causation” standards to prevent expansive constructions of the AKS that would otherwise be a “trap for the unwary” and could result in the prosecution of those acting with “good intent.” *U.S. ex rel. Hart v. McKesson Corp.*, 96 F.4th 145, 155–57, 161 (2d Cir. 2024) (ruling that plaintiff must show defendant acted with a “bad purpose,” that is, “the defendant must act with knowledge that his conduct was unlawful” and concluding that the AKS’s purpose is to punish those who act with a “vicious will” and observing that a more expansive reading “would risk creating a trap for the unwary and deter socially beneficial conduct” (internal quotation marks and citations omitted)); *see also Martin*, 63 F.4th at 1054 (concluding that “reading causation too loosely or remuneration too broadly appear as opposite sides of the same problem. Much of the workaday practice of medicine might fall within an expansive interpretation of the [AKS]. Worse

still, the statute does little to protect doctors of good intent, sweeping the vice-ridden and virtuous alike” (citation omitted)).

Third, while the AKS does not define the word “remuneration,” courts have defined remuneration to be a price that exceeds fair market value. *See, e.g., Bingham v. HCA, Inc.*, 783 F. App’x 868, 873–74 (11th Cir. 2019) (finding that an AKS violation “requires that there be ‘remuneration’ offered or paid in the transaction at issue” and that no remuneration exists if payment is made at fair market value); *see also Bingham v. Baycare Health Sys.*, No. 8:14-cv-73-T-23JSS, 2016 U.S. Dist. LEXIS 186016, at *18 (M.D. Fla. Dec. 16, 2016); *U.S. ex rel. Fair Lab. Practices Assocs. v. Quest Diagnostics, Inc.*, No. 05 Civ. 5393 (RPP), 2011 U.S. Dist. LEXIS 37014, at *9 (S.D.N.Y. Mar. 24, 2011).

“Remuneration” does not include “any amount paid by an employer to an employee (who has a bona fide employment relationship with such employer) for employment in the provision of covered items or services.” 42 U.S.C. § 1320a-7b(b)(3)(B); *accord* 42 C.F.R. § 1001.952(i). However, the fact that the AKS has a statutory exception and regulatory safe harbor exempting payments of remuneration to employees does *not* mean that payments made to non-employees are automatically within the scope of the AKS. Compliance with a statutory exception or safe harbor is voluntary, and no company is required to comply with either a statutory exception or safe harbor. *See Medicare and State Health Care Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements*, 85 Fed. Reg. 77,684, 77,752 (Dec. 2, 2020) (“Safe harbors offer voluntary protection from liability under the Federal anti-kickback statute for specified arrangements, and no entity or individual is required to fit within a safe harbor. Failure to fit within a safe harbor does not mean a party has violated—or even implicated—the Federal anti-kickback statute, it simply means the party may not

look to the safe harbor for protection for that arrangement.”); *see also id.* at 77,689 (“[C]ompliance with an anti-kickback statute safe harbor is voluntary, and there are many arrangements that do not fit in a safe harbor that are lawful under the anti-kickback statute. Deviating from a safe harbor does not mean that an arrangement violates the anti-kickback statute.”). The AKS does not expressly bar payments made to independent contractors or bar payments made to sales representatives paid on a commissioned basis.

Fourth, remuneration must be paid to induce a “person” to refer an “individual.” For purposes of the AKS, an individual is “not an artificial entity.” *S&G Labs Haw., Ltd. Liab. Co. v. Graves*, No. 19-00310 LEK-WRP, 2021 U.S. Dist. LEXIS 200365, at *31–32 (D. Haw. Oct. 18, 2021); *see also* 42 U.S.C. § 1301(a)(3) (defining “person” as an “individual” or “a trust or estate, a partnership, or a corporation”). Hence, the AKS does not apply unless the unlawful remuneration paid is knowingly and willfully intended to be the but-for cause for the referral of individuals.

2. EKRA

Like the AKS, EKRA prohibits a person from “*knowingly and willfully*” paying “*remuneration*” to “*induce*” the “*refer[r]al of an individual*” for which payment is made under a Federal health care program:

(a) Offense.--Except as provided in subsection (b), whoever, with respect to services covered by a health care benefit program, in or affecting interstate or foreign commerce, **knowingly and willfully**-- ...

(2) pays or offers any **remuneration** (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—

(A) to **induce a referral of an individual** to a recovery home, clinical treatment facility, or laboratory...

shall be fined not more than \$200,000, imprisoned not more than 10 years, or both, for each occurrence.

18 U.S.C. § 220 (emphasis added). Courts construing EKRA have used case law precedent under the similarly worded AKS to construe like terms in EKRA. *See, e.g., GF Indus. of Mo., LLC v. Lehigh Valley Genomics, LLC*, No. 22-227, 2024 U.S. Dist. LEXIS 78245, at *31 (E.D. Pa. Apr. 30, 2024) (“To understand the phrase ‘induce a referral of an individual’ in EKRA, we find helpful the meaning of nearly analogous language in the AKS.”); *Graves*, 2021 U.S. Dist. LEXIS 200365, at *30.

EKRA also provides a statutory safe harbor that protects payments an employer makes to “an employee or independent contractor (who has a bona fide employment or contractual relationship with such employer) for employment, if the [] payment is not determined by or does not vary by the number of individuals referred to a particular recovery home, clinical treatment facility, or laboratory; the number of tests or procedures performed; or the amount billed to or received from, in part or in whole, the health care benefit program from the individuals referred to a particular recovery home, clinical treatment facility, or laboratory.” 18 U.S.C. § 220(b)(2). Like the AKS, this exception is voluntary, and failure to comply with the statutory exception does not mean that EKRA was breached. *See Graves*, 2021 U.S. Dist. LEXIS 200365, at *34–35 (ruling that failure to comply with EKRA exception “does not mean [the] compensation violated EKRA” because the “exception is only relevant if there is a violation of [EKRA] in the first instance” and because the sales representative’s “compensation did not violate [EKRA, EKRA’s] exception is irrelevant to this case”); *accord Lehigh Valley Genomics, LLC*, 2024 U.S. Dist. LEXIS 78245, at *29 n.5.

3. The FCA

To establish an FCA violation, Relator must show that Defendants presented or caused the presentation, of false claims, knowingly, that were material to the government’s determination to

pay. *See U.S. ex rel. King v. Solvay Pharms., Inc.*, 871 F.3d 318, 324 (5th Cir. 2017) (providing that an “FCA claim consists of four elements: (1) whether there was a false statement or fraudulent course of conduct; (2) made or carried out with the requisite scienter; (3) that was material; and (4) that caused the government to pay out money or to forfeit moneys due (*i.e.*, that involved a claim)” (internal quotation marks and citation omitted)). Relevant here are the FCA’s falsity, knowledge and causation elements.

As to FCA falsity, to be “false” under the FCA, a claim must be inconsistent with the governing statute, regulation, or rule that authorizes it. *United States v. Southland Mgmt. Corp.*, 326 F.3d 669, 674–75 (5th Cir. 2003). When there is no violation of a statute, regulation or rule, courts hold that as a matter of law, there cannot be an FCA violation. *See id.*; *see also Thulin v. Shopko Stores Operating Co., LLC*, 771 F.3d 994, 998–1000 (7th Cir. 2014); *Luckey v. Baxter Healthcare Corp.*, 183 F.3d 730, 732 (7th Cir. 1999); *U.S. ex rel. Gudur v. Deloitte Consulting, LLP*, 512 F. Supp. 2d 920, 948 (S.D. Tex. 2007), *aff’d sub nom. U.S. ex rel. Gudur v. Deloitte & Touche*, No. 07-20414, 2008 U.S. App. LEXIS 17038 (5th Cir. Aug. 7, 2008); *United States v. Prabhu*, 442 F. Supp. 2d 1008, 1026 (D. Nev. 2006); *United States v. Medica-Rents Co.*, 285 F. Supp. 2d 742, 770–71 (N.D. Tex. 2003), *aff’d in relevant part*, No. 03-11297, 2008 U.S. App. LEXIS 17946 (5th Cir. Aug. 19, 2008). Further, to be false under the FCA, a statement must be objectively false. *See U.S. ex rel. Harman v. Trinity Indus.*, 872 F.3d 645, 656 (5th Cir. 2017); *U.S. ex rel. Wilson v. Kellogg Brown & Root*, 525 F.3d 370, 377–78 (4th Cir. 2008); *see also U.S. ex rel. Farmer v. City of Houston*, 523 F.3d 333, 340 n.12 (5th Cir. 2008); *U.S. ex rel. Morton v. A Plus Benefits, Inc.*, 139 F. App’x 980, 982 (10th Cir. 2005); *U.S. ex rel. Jamison v. McKesson Corp.*, 784 F. Supp. 2d 664, 676–77 (N.D. Miss. 2011); *Prabhu*, 442 F. Supp. 2d at 1032–33.

As to scienter, here, because both statutes that Relator claims Defendants breached—the AKS and EKRA—require that they be breached “knowingly and willfully,” Relator must establish that Defendants acted with that intent. But even under the lower FCA scienter standard, Relator must establish, at a minimum, that Defendants acted in reckless disregard or deliberate ignorance of the truth or falsity of any claim. 31 U.S.C. § 3729(b). Mere negligence is insufficient. *See U.S. ex rel. Jacobs v. Walgreen Co.*, No. 21-20463, 2022 U.S. App. LEXIS 5502, at *2 (5th Cir. Mar. 2, 2022) (affirming dismissal at pleading stage because relator’s amended complaint “provided ten ‘examples’ of [defendant’s] allegedly fraudulent billing practices, none of which pleaded facts supporting an inference that the allegedly fraudulent conduct amounted to anything more than innocent mistake or negligence. Our precedent is clear: th[e] mens rea requirement [of an FCA claim] is not met by mere negligence or even gross negligence” (internal quotation marks and citations omitted)). And, as this circuit has recognized, the more ambiguous the underlying law, the less likely that any knowing violation under the FCA occurred. *See, e.g., Farmer*, 523 F.3d at 342 (“[T]he jury would necessarily assess how obvious it should have been to defendants that they were violating the regulations: the more obvious the violation, the more rational the inference that defendants were acting knowingly. Here, however, the violation is not obvious at all The presence of this ambiguity makes it less likely that the jury would conclude that a violation—if, indeed, there was one—of the provision means that defendants acted with reckless disregard for the truth, especially given the limited case law interpreting the provision.” (footnote omitted)).

As to FCA causation, causation is not established by virtue of simply alleging corporate defendants are affiliated.⁴ Instead, to establish FCA causation, a plaintiff must demonstrate that a party has taken an “affirmative action” that “cause[d] or assist[ed] the presentation of a fraudulent claim.” *Sikkenga*, 472 F.3d at 714–15. Courts thus analyze a party’s specific conduct to determine “whether that specific conduct cause[d] the presentment of a false claim.” *Id.* at 714. This requirement ensures that only FCA claims “against parties who can fairly be said to have caused a claim to be presented to the government” proceed, while “claims with only attenuated links between the defendants’ specific actions and the presentation of the false claim” are barred. *United States v. Luce*, 873 F.3d 999, 1012–13 (7th Cir. 2017) (quoting *Sikkenga*, 472 F.3d at 714).

II. THE COURT SHOULD DISMISS RELATOR’S CLAIMS

A. Relator’s FAC Fails to Comply with Rule 12(b)(6)

⁴ See *U.S. ex rel. Schaengold v. Mem’l Health, Inc.*, No. 4:11-cv-58, 2014 U.S. Dist. LEXIS 169555, at *27 (S.D. Ga. Dec. 8, 2014) (“[M]erely being a parent, or an associated corporation, of a subsidiary that commits an FCA violation is insufficient to support an FCA action against the parent or the associated corporation.” (citation omitted)); *see also, e.g., U.S. ex rel. Lisitza v. PAR Pharm. Cos.*, No. 06 C 06131, 2013 U.S. Dist. LEXIS 31224, at *17 (N.D. Ill. Mar. 7, 2013) (“Parent firms are not generally liable for the misdeeds of their subsidiaries, and the FCA does not alter that general rule.” (citing *United States v. Bestfoods*, 524 U.S. 51, 61 (1998))); *U.S. ex rel. Saltzman v. Textron Sys. Corp.*, No. 09-11985-RGS, 2011 U.S. Dist. LEXIS 61994, at *7 (D. Mass. June 9, 2011) (refusing to disregard separate identities of a parent and subsidiary and dismissing relator’s allegations against parent company and ultimate parent when relator failed to allege sufficient facts to connect them to the alleged misconduct of the subsidiary and stating that “[o]wnership – even total ownership – of a corporation does not by itself impart the corporation’s liabilities to the owner, and that rule is not abated simply because the owner happens to be another corporation” (internal quotation marks and citation omitted)). Additionally, merely asserting that one corporate entity knows what another entity is doing is insufficient to demonstrate FCA causation. See *U.S. ex rel. Sikkenga v. Regence Bluecross Blueshield*, 472 F.3d 702, 714 (10th Cir. 2006) (“Generally, mere knowledge of the submission of claims and knowledge of the falsity of those claims is insufficient to establish liability under the FCA.” (citation omitted)), abrogated on other grounds, *Cochise Consultancy, Inc. v. U.S. ex rel. Hunt*, 139 S. Ct. 1507 (2019).

To survive a Rule 12(b)(6) motion to dismiss, a relator must plead “enough facts to state a claim to relief that is plausible on its face,” so as to “nudge[] [his] claim[] across the line from conceivable to plausible.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). “A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citation omitted). At a minimum, these standards “require[] more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do.” *Twombly*, 550 U.S. at 555 (citation omitted); *see also U.S. ex rel. Integra Med Analytics, LLC v. Baylor Scott & White Health*, 816 F. App’x 892, 897–99 (5th Cir. 2020) (finding that under the FCA, a “claim is merely conceivable and not plausible if the facts pleaded are consistent with both the claimed misconduct and a legal and obvious alternative explanation”); *U.S. ex rel. Shupe v. Cisco Sys.*, 759 F.3d 379, 382 (5th Cir. 2014) (“The plaintiff’s factual allegations must support a claim to relief that . . . rises above mere speculation.”).

To satisfy Rule 12(b)(6) in an FCA case, Relator must plausibly plead, at a minimum, FCA falsity, knowledge, and causation. *See Harman*, 872 F.3d at 653–54 (describing elements). Because Relator cannot plausibly plead FCA falsity, knowledge, or causation, Relator’s FCA claims (Counts I–III) should be dismissed under Rule 12(b)(6). Similarly, Relator’s Count IV (FCA conspiracy) should be dismissed because Relator does not plead a substantive cause of action and because Relator’s conspiracy claim is foreclosed under the intracorporate conspiracy doctrine.

1. Relator’s FAC Does Not Plausibly Plead an FCA Violation

As an initial matter, Relator cannot plausibly plead FCA falsity. Relator asserts that Defendants presented, or caused to be presented, expressly or impliedly false certifications that Apollo Labs’s or Arbor’s claims were in compliance with the AKS or EKRA when, in fact, they

were out of compliance with those statutes because Defendants allegedly paid independent contractor sales commissions based on the profitability of sales. *See ECF 52 ¶¶ 2, 4.* Relator is wrong because (i) nothing in the plain language of the AKS or EKRA prohibits the payment of sales commission based upon the profitability of sales and (ii) case law directly rebuts Relator's contention that these statutes prohibit the payment of sales commissions to independent contractors based on the profitability of sales.

(a) Relator's Interpretation of Law Is Inconsistent with the Plain Language of the Relevant Statutes, and Thus Relator Does Not Plausibly Plead FCA Falsity

First, the allegations in Relator's Complaint do not satisfy the FCA's falsity element because the practices alleged, even assuming they are accurate (which they are not), do not violate EKRA or the AKS under the plain language of those statutes. EKRA and the AKS proscribe laboratories from paying persons "remuneration" to induce a referral of an "individual." Relator's AKS and EKRA claims are, therefore, fatally flawed because, Relator never plausibly claims that any sales representative was paid above fair market value, and thus, under these statutes, no unlawful remuneration was paid to them.⁵ *See Bingham*, 783 F. App'x at 873–74; *Baycare Health*

⁵ Relator's initial Complaint did not allege that any Defendant paid any sales representative a kickback. Defendants pointed out in their Memorandum in Support of Dismissal that this, by itself, was grounds for dismissal because, by definition, no unlawful remuneration would have been paid under the AKS or EKRA. *See ECF 50* at 13. Now, more than four years into this litigation, after reading Defendants' Motion to Dismiss, Relator suddenly alleges, in a conclusory fashion, that some alleged unspecified criminal kickbacks were, indeed, paid by some unidentified Defendant to some unidentified sales representative on some unidentified date because fair market value was not paid, as "[s]ome sales reps were paid nearly ten times as much as other sales reps." *ECF 52 ¶¶ 234–35.* This is defective for at least two reasons.

First, as courts have noted, this type of amendment in a long-running FCA case reflects bad faith. Given the structure of the FCA, which mandates that such information be identified in the Complaint so the government can investigate, 31 U.S.C. § 3730(b), and Rule 9(b), which mandates that Defendants be able to discern what exactly is alleged against them, one appellate

Sys., 2016 U.S. Dist. LEXIS 186016, at *18; *Quest Diagnostics, Inc.*, 2011 U.S. Dist. LEXIS 37014, at *9. In addition, Relator does not allege that sales representatives referred “individuals”—*i.e.*, patients. Instead, he alleges that sales representatives had relationships with independent physicians, medical practices, and facilities that, in turn, referred individual patients for laboratory services. *See, e.g.*, ECF 52 ¶¶ 220–22, 230 (outlining sales representatives’ relationships with providers—not individual patients). Accordingly, because Relator does not plead either the plausible payment of unlawful “remuneration” or that the sales representatives who were allegedly receiving remuneration referred “individuals” (as opposed to actual providers referring individual patients), Relator does not plausibly plead a violation of either statute under the plain language of these statutes; hence, he cannot establish that Defendants made false certifications in compliance with these statutes. *See Graves*, 2021 U.S. Dist. LEXIS 20035, at *34

court recently noted that amendments like this one—where a relator fails to explain why such information was held back for purposes of an amendment rather than pleaded in the initial complaint so that the government, consistent with the statute, could discharge its statutory duty to investigate and which led to Defendants being put to the cost of preparing a Motion to Dismiss—evidence bad faith. *See, e.g.*, *U.S. ex rel. Nicholson v. MedCom Carolinas, Inc.*, 42 F.4th 185, 199 (4th Cir. 2022) (ruling that a factor in finding bad faith could include relator waiting, like here, four years to amend a complaint with additional alleged facts).

Second, in any event, the conclusory allegation does not support a plausible FCA claim. Relator’s contention that a criminal kickback was paid because some sales representatives were allegedly paid “nearly ten times as much as other sales reps,” ECF 52 ¶¶ 234–35, says nothing about whether criminal kickbacks were paid. Differentials in payment of employees and contractors is common in all industries based on productivity, performance, and expertise, and there is not any law saying that all employees and contractors must be paid the same amount regardless of productivity, performance, or expertise. As this circuit has recognized, a claim is “not plausible if the facts pleaded are consistent with both the claimed misconduct and a legal and obvious alternative explanation.” *Integra Med Analytics, LLC* 816 F. App’x at 897–99.

(finding that because a sales representative “was not working with individuals, the compensation [the laboratory] paid him was not paid to induce him to refer individuals” to the laboratory).⁶

Second, aside from operating under a mistaken interpretation of law and proceeding with a legal theory that is contrary to the plain language of EKRA and the AKS, Relator cannot plead a false claim because case law, including cases issued after Relator filed his Complaint, directly undermine Relator’s claim. In construing both the AKS’s and EKRA’s language in the context of sales representatives and marketers, courts, including the Fifth Circuit, distinguish between those who perform, in essence, advertising or promotion roles with respect to items and services (which does not run afoul of these statutes) and those decisionmakers who directly interact with patients and have the ability to make referrals (which could run afoul of these statutes). *See United States v. Miles*, 360 F.3d 472, 479–81 (5th Cir. 2004).⁷

⁶ As noted, neither the plain language of the AKS nor EKRA prohibits paying sales commissions to independent contractors. It could be that Relator is contending that Defendants breached the AKS and EKRA because they did not satisfy the AKS and EKRA safe harbor for employees. *See, e.g.*, ECF 52 ¶¶ 92–93, 96. But even assuming for purposes of this motion that these safe harbors were not satisfied, Relator has not pleaded a cause of action because one may fully comply with both statutes without satisfying EKRA’s exception or the AKS employment safe harbor. *See Graves*, 2021 U.S. Dist. LEXIS 200365, at *34–35; *Lehigh Valley Genomics, LLC*, 2024 U.S. Dist. LEXIS 78245, at *29 n.5; *see also* 85 Fed. Reg. at 77,689, 77,752.

⁷ The statutory foundation for this distinction is the language, in both EKRA and the AKS, that requires the payment of remuneration be made “to induce a referral.” As the district court explained in *Lehigh Valley Genomics, LLC*:

Black’s Law Dictionary defines “referral” as “[t]he act or an instance of **sending or directing to another** for information, service, consideration, or decision.” *Referral*, *Black’s Law Dictionary* (11th ed. 2019) (emphasis added). However, it defines “advertising” as “[t]he action of drawing the public’s attention to something to promote its sale.” *Advertising*, *Black’s Law Dictionary* (11th ed. 2019). Thus, an attempt to “induce a referral” connotes a more active attempt to recruit individuals than does mere “advertising.”

2024 U.S. Dist. LEXIS 78245, at *34–35 (emphasis in original) (footnote omitted).

Indeed, directly contrary to Relator’s position here, the Fifth Circuit, just earlier this year, in *United States v. Marchetti*, reiterated that “it is legally correct to say that percentage-based compensation structures are not *per se* unlawful.” 96 F.4th 818, 831 (5th Cir. 2024). Indeed, to prove a violation of law, the “structure of the contract alone is not sufficient evidence to produce a conviction under the [AKS].” *Id.* at 826. Rather, a plaintiff needs to provide some detail about how the sales representative improperly influenced those who make healthcare decisions. *Id.* at 827. Here, Relator does not plead any facts asserting that sales representatives had direct contact with patients and unduly influenced them, or that the sales representatives improperly corrupted the decision-making of healthcare professionals in making their referral decisions, as opposed to merely promoting or advertising Defendants’ services.⁸ Accordingly, because the mere structure

⁸ The core of Relator’s mistaken application of the AKS, and by extension EKRA, resides in his misunderstanding of how this circuit defines and applies what is a “referral” under the AKS. As this circuit pointed out in *United States v. Cooper*, the AKS does not define the word “refer.” 38 F.4th 428, 432–33 (5th Cir. 2022). The court noted that “[w]hen interpreting statutes, [w]ords are to be understood in their everyday meanings—unless the context indicates that they bear a technical sense.” *Id.* (quoting *Thomas v. Dep’t of Educ. (In re Thomas)*, 931 F.3d 449, 454 (5th Cir. 2019)) (internal quotation marks omitted). The court observed, given the AKS’s medical context, that “the word ‘refer’ should be given a technical meaning.” *Id.* at 433 (citation omitted). The court concluded that this technical definition of “refer” “includes not only a doctor’s recommendation of a provider, but also a doctor’s *authorization* of care of a particular provider.” *Id.* (internal quotation marks and citation omitted). Crucially, “the referrer typically serves a gatekeeping role, facilitating or approving a patient’s choice of provider.” *Id.* (internal quotation marks and citation omitted).

Rather than use this technical definition focusing on the gatekeeper—that is, the physician, medical practice, or healthcare facility, i.e., the actual decisionmaker regarding where the patients receive healthcare—Relator continuously, in his FAC, states loosely, and contrary to Fifth Circuit authority, that the sales representatives are making “referrals,” without alleging any facts asserting that these sales representatives unlawfully influenced the gatekeeping decisionmakers who actually directed patient care, such as paying them kickbacks or otherwise exercising undue influence over their healthcare decisions impacting their patients. *See, e.g.*, ECF 52 ¶¶ 28, 152, 194, 198–99, 205–06, 240, 308, 312 (representing, without any support and contrary to the Fifth Circuit’s definition of the term as used in the statute, that sales representatives made “referrals” of patient specimens as opposed to the independent physicians, medical practices, and healthcare

of the contract is insufficient to constitute a violation of these laws, and because Relator pleads nothing else, Relator fails to plead a plausible claim. *See Marchetti*, 96 F.4th at 831; *Miles*, 360 F.3d at 479–81; *see also Lehigh Valley Genomics, LLC*, 2024 U.S. Dist. LEXIS 78245, at *35–36 (applying these principles to EKRA and noting that “[t]herefore, like in *Marchetti*, the structure of the contract alone is not sufficient evidence to show a violation of EKRA” and concluding that “providing marketing services and being compensated based on the success of those services” is not “specifically proscribed by EKRA” (internal quotation marks and citations omitted)).⁹

facilities). It was precisely this same error that led this Circuit in *Marchetti* to reject several of the government’s AKS claims because the government (i) never described how the marketers receiving the percentage-based compensation “interacted with relevant decisionmakers” (e.g., physicians); (ii) did not “provide a drop of color as to what the [marketer’s] influence looked like”; and (iii) failed to provide “any detail on the key relationship: the relationship between [the marketer] and the relevant decisionmakers,” leading the court to conclude that “this is where the government dropped the ball” because it never established that the marketers exercised any improper influence over those who make healthcare decisions. 96 F.4th at 826–27.

Here, Relator has “dropped the ball” in the same fashion, because he never pleads any facts regarding any improper influence any sales representative exercised over any physician, medical practice, or healthcare facility in the provision of care to its patients. Indeed, Relator openly acknowledges that he cannot do this because Defendants do not know what, if any, relationship existed between the gatekeeper clinicians and sales representatives. ECF 52 ¶ 159 (“Neither the Defendant entities nor their agents monitored or questioned the nature of any agreements between healthcare service providers and sales reps. As a result, they were unaware of any kickback arrangements between ALS sales reps with healthcare providers or their staff”). Accordingly, because percentage-based compensation structures by themselves do not breach the AKS, but instead “something more” in the form of improper influence over the decisionmaker must be shown, which Relator does not plead here, Relator does not plausibly plead a violation of the AKS or EKRA.

⁹ Cf. *United States v. Schena*, No. 5:20-cr-00425-EJD-1, 2022 U.S. Dist. LEXIS 96051, at *3, *12 (N.D. Cal. May 28, 2022) (finding government could assert EKRA claim when defendant paid kickbacks to marketer and distributed fraudulent marketing material to physicians to improperly influence tests physicians would order). Here, by contrast, there is no contention that any false or fraudulent materials were submitted to physicians that improperly influenced their referral decisions.

Thus, because Relator does not plausibly plead that Defendants presented false certifications of compliance with law, the Court should dismiss Relator's FCA action because Relator cannot satisfy the FCA's falsity element. *See Southland Mgmt. Corp.*, 326 F.3d at 674–75; *Thulin*, 771 F.3d at 998–1000; *Luckey*, 183 F.3d at 732; *Gudur*, 512 F. Supp. 2d at 948; *Prabhu*, 442 F. Supp. 2d at 1026; *Medica-Rents Co.*, 285 F. Supp. 2d at 770–71.

(b) Relator Does Not Plausibly Plead that Defendants Acted with the Requisite Scienter

To violate either EKRA or the AKS, a plaintiff must establish that the defendant “knowingly and willingly” intended to engage in conduct in violation of those statutes. *See* 18 U.S.C. § 220(a) (emphasis added); 42 U.S.C. § 1320a-7b(b) (emphasis added).

To plausibly plead that Defendants knowingly and willfully paid remuneration to induce referrals, Relator must plead facts showing that Defendants knew that their conduct was wrongful and acted with a “bad purpose.” *See Shah*, 95 F.4th at 350; *Nora*, 988 F.3d at 830–31; *Ricard*, 922 F.3d at 648; *see also, generally*, *Hart*, 96 F.4th at 155–57.

Here, there are at least a couple of reasons that Relator does not plausibly plead a knowing and willful violation of law. *First*, Relator does not plausibly plead that Defendants knowingly and willfully paid remuneration in violation of law for the simple reason that, as noted, neither EKRA nor the AKS prohibits the payment of commissions to independent contractors based on their sales; hence, Defendants could not have known, by definition, that they were operating in violation of law. *See Lehigh Valley Genomics, LLC*, 2024 U.S. Dist. LEXIS 78245, at *35–36; *Graves*, 2021 U.S. Dist. LEXIS 20035, at *34; *see also Marchetti*, 96 F.4th at 831; *Miles*, 360 F.3d at 479–81.

Second, even if contrary to the laws' plain language, one were to construe the statutory language as ambiguous regarding (i) what constitutes "remuneration"; (ii) whether the sales representatives were paid remuneration to "refer" an "individual"; or (iii) whether the mere structure of a commission contract, by itself, could constitute an AKS or EKRA violation, this further establishes that Defendants could not have knowingly and willfully violated the law. Even under the FCA's lower scienter standard, the more ambiguous the statute giving rise to the alleged false statement, the less likely that one operated with reckless disregard or deliberate ignorance in presenting the false statement. *See, e.g., Farmer*, 523 F.3d at 342.¹⁰ Thus, because Defendants' conduct complied with law and Relator does not plead any plausible grounds for non-compliance, Relator cannot show that Defendants acted with the requisite scienter.

(c) Relator's FAC Does Not Plead Plausible Causation

Under Counts I and II, each Defendant must either "present" or "cause to be presented" a false or fraudulent claim for payment. 31 U.S.C. § 3729(a)(1)(A)–(B). Here, Relator contends that Apollo Labs presented false claims to government healthcare programs. *See* ECF 52 ¶ 21. But Relator cannot establish FCA causation for multiple reasons.

¹⁰ Similarly, under the AKS and EKRA, the rule of lenity would "break the tie in [Defendants'] favor" (although, here, in light of these statutes' plain language and court precedent, there is no "tie"). *Cooper*, 38 F.4th at 434 (applying rule of lenity in AKS action and observing that rule requires ambiguous criminal laws to be interpreted in favor of the defendants subjected to them); *Lehigh Valley Genomics, LLC*, 2024 U.S. Dist. LEXIS 78245, at *29 n.24 (applying rule of lenity to EKRA and noting that rule of lenity can apply in civil context); *see also Martin*, 63 F.4th at 1050 (in applying the AKS in an FCA action observing that the same language in the AKS "creates civil *and* criminal liability" and in "the context of dual-application statutes like this one, we give the same interpretation to the same words, whether applied in a civil or criminal setting," which "means that, if ambiguity exists over the meaning of a provision, the rule of lenity favors the narrower definition" (citations omitted)).

First, as to the AKS, Relator does not plausibly plead causation because he must plausibly plead that the alleged kickback (the percentage-based compensation structure paid to sales representatives) was the but-for cause of the decision of independent physicians, medical practices, and healthcare facilities to make referrals of patient specimens to Apollo Labs and Arbor, and Relator pleads *no* such facts—let alone *plausible* facts. *See Martin*, 63 F.3d at 1052; *Cairns*, 42 F.4th at 834–35. Indeed, he acknowledges that he cannot plead any such facts because he does not know of any kickback between healthcare providers and sales representatives that would influence the healthcare providers in electing to use Apollo Labs. ECF 52 ¶ 159.

Second, to plausibly plead that ALS, Korenvaes Management, LLC, David Key, Brian Oliver, or Max Korenvaes “caused” Apollo Labs or Arbor to present allegedly knowingly false claims to the government, Relator would have to plead plausible facts showing that each undertook “affirmative action” to cause specific sales representatives to exercise unlawful influence over medical gatekeepers and decisionmakers in their healthcare referral decisions; Relator, again, pleads no such facts—let alone plausible facts. *See, e.g., Sikkenga*, 472 F.3d at 714–15; *see also* ECF 52 ¶ 159.¹¹

2. Relator’s Conspiracy Claim (Count IV) Should Also be Dismissed under Rule 12(b)(6)

¹¹ For the same reasons that Relator does not state a substantive FCA cause of action (Counts I and II), Relator’s reverse false claim cause of action (Count III), under 31 U.S.C. § 3729(a)(1)(G), fails. When Relator, as here, does not show any plausible overpayment was received, Defendants cannot have knowingly retained an overpayment under the FCA’s reverse false claims provision. *See U.S. ex rel. Guth v. Roedel Parsons Koch Balhoff & McCollister*, 626 F. App’x 528, 534 (5th Cir. 2015); *see also United States v. Cath. Health Initiatives*, No. 4:18-CV-123, 2022 U.S. Dist. LEXIS 122157, at *32 (S.D. Tex. Mar. 31, 2022) (finding that defendants’ failure to refund “the same money the Government allegedly paid in relation to [Relator’s] § 3729(a)(1)(A) and (B) claims” is not, itself, actionable under the reverse False Claims Act provision).

Count IV alleges a violation of 31 U.S.C. § 3729(a)(1)(C) for conspiracy to defraud the government. Relator's conspiracy claim fails for at least three reasons. First, Relator's FAC sets forth no facts as to any alleged conspiracy. Second, a conspiracy claim fails when Relator fails to plead a substantive FCA violation. *See U.S. ex rel. Godfrey v. KBR, Inc.*, 360 F. App'x 407, 413 (4th Cir. 2010) ("Since [the relator's] conspiracy claim is premised on those claims of underlying FCA violations, the conspiracy claim rises and falls with the individual claims."). Because there is no valid underlying FCA claim alleged, there can be no conspiracy. Third, the FCA's conspiracy provision does not apply to related entities, and Relator here claims that all Defendants are affiliated with each other. *See, e.g., Hawaii ex rel. Torricer v. Liberty Dialysis-Hawaii LLC*, 512 F. Supp. 3d 1096, 1118 (D. Haw. 2021) ("[T]he conspiracy claims also fail because, at best, the [first amended complaint] alleges that the Defendants are all affiliated with one another. . . . The conspiracy claims are thus barred by the intracorporate conspiracy doctrine, under which as a matter of law, a corporation cannot conspire with its own employees or agents." (internal quotations and citations omitted)); *see also U.S. ex rel. Hagerty v. Cyberonics, Inc.*, 95 F. Supp. 3d 240, 270 (D. Mass. 2015), *aff'd*, 844 F.3d 26 (1st Cir. 2016); *Parker v. Sea-Mar Cnty. Health Ctr.*, No. C18-5395RBL, 2020 U.S. Dist. LEXIS 74644, at *23–24 (W.D. Wash. Apr. 28, 2020); *U.S. ex rel. Fisher v. IASIS Healthcare LLC*, No. CV-15-00872-PHX-JJT, 2016 U.S. Dist. LEXIS 155517, at *54–57 (D. Ariz. Nov. 8, 2016); *U.S. ex rel. Harper v. Muskingum Watershed Conservancy Dist.*, No. 5:13-cv-2145, 2015 U.S. Dist. LEXIS 159326, at *30–32 n.11 (N.D. Ohio Nov. 25, 2015), *aff'd*, 842 F.3d 430 (6th Cir. 2016); *U.S. ex rel. Rector v. Bon Secours Richmond Health Corp.*, Civil Action No. 3:11-CV-38, 2014 U.S. Dist. LEXIS 52161, at *36–38 (E.D. Va. Apr. 14, 2014); *see also* ECF 52 ¶¶ 15–61, 254–306.

B. Relator’s FCA Allegations Fail to Meet Rule 9(b)’s Heightened Pleading Requirements

The FCA is a fraud statute. Thus, Relator’s allegations must satisfy Rule 9(b)’s stringent pleading requirements. *U.S. ex rel. Doe v. Dow Chem. Co.*, 343 F.3d 325, 328 (5th Cir. 2003). To satisfy Rule 9(b), Relator must plead the “who, what, when, where, and how” of the alleged fraud. *U.S. ex rel. Colquitt v. Abbott Labs.*, 858 F.3d 365, 371 (5th Cir. 2017) (citation omitted). Additionally, Relator must allege the specifics of an actually submitted false claim, or, if he cannot allege the specific details of a false claim, he must allege the “particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted.” *U.S. ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 190 (5th Cir. 2009); *see also Colquitt*, 858 F.3d at 372. To survive the “particular details of a scheme to submit false claims” prong, Relator must do more than allege a conclusory scheme. *Colquitt*, 858 F.3d at 372.

Relator does not plead a cause of action with specificity because he does not identify any federal healthcare claim or state with strong indicia of reliability a single occasion in which *any* Defendant caused any sales representative to pay a kickback to a healthcare decisionmaker, or otherwise unlawfully influence any healthcare decisionmaker, to make a referral of a specimen to Apollo Labs or Arbor. Specifically, Relator does not allege any facts regarding any specific instance in which any Defendant allegedly caused any specific sales representative to exercise unlawful influence over a referral decision of any patient specimen, such as (i) who the Defendant was, (ii) who the sales representative was, (iii) what the unlawful influence over the healthcare decisionmaker’s referral decision was, or (iv) who the patient was; hence, he does not allege the “who, what, when, where, and how” of the alleged fraud. *See id.* at 371; *Integra Med Analytics, L.L.C.*, 816 F. App’x at 900 (holding Rule 9(b) not satisfied when relator alleges a general scheme

but does not link to any defendant details of an alleged fraud claim). Indeed, Relator admits that he cannot do this. *See* ECF 52 ¶ 159.

III. CONCLUSION

For the foregoing reasons, the Court should dismiss Counts I–IV in Relator’s FAC with prejudice.¹²

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Respectfully submitted,

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¹² Because Relator’s federal FCA claims fail, the Court should decline to exercise jurisdiction over his state law claims (Counts V–VIII). *See, e.g., Jacobs*, 2022 U.S. App. LEXIS 5502, at *3–4; *United States v. Kimberly-Clark*, No. 3:15-CV-0434-B, 2017 U.S. Dist. LEXIS 154975, at *15–16 (N.D. Tex. Sept. 22, 2017); *U.S. ex rel. Williams v. McKesson Corp.*, No. 3:12-CV-0371-B, 2014 U.S. Dist. LEXIS 92987 at *26–27 (N.D. Tex. July 9, 2014).

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CERTIFICATE OF SERVICE

This is to certify that I, Elizabeth Scott, one of the attorneys for Defendants, individually and on behalf of all Defendants, have this day furnished a true and correct copy of the above and foregoing **DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF THEIR MOTION TO DISMISS AMENDED COMPLAINT** to the following via ECF filing:

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This 4th day of November, 2024.

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